

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406054	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Centracare - Sauk Centre	Street Address, City, State 425 Elm Street North, Sauk Centre, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document maintenance activities for Immunochemistry equipment as required in 2022 and 2023. Findings are as follows: 1. The laboratory performed Immunochemistry testing as confirmed by the General Supervisor during a tour of the laboratory at 8:05 a.m. on 02/16/23. 2. The LISS dispenser was observed in the Immunochemistry area of the laboratory as present and available for use during the tour. 3. LISS dispenser weekly cleaning was required as established in the LISS Dispenser Cleaning and Calibration procedure found in the laboratory's electronic procedure program PolicyStat. 4. The LISS Dispenser Cleaning and Calibration Log indicated weekly cleaning was performed consistently from 11/11/21 through 07/21/22 and cleaning after 07/21/22 was performed intermittently. See below Date Date Weeks elapsed 07/21/22 10/15/22 12.4 10/15/22 01/06/23 12 01/06/23 01/23/23 2.6 01/23/23 02/02/23 1.6 02/02/23 N/A 2.1* *Date of survey, 02/16/23, used for calculation 5. In an interview at 3:50 p.m. on 02/16/23, Testing Personnel 1 confirmed the above finding and indicated the LISS dispenser weekly cleaning had been performed but was not documented. .</p>
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to identify and correct unacceptable comparison results for one of eight Chemistry analytes in 2022 and one of eight Chemistry analytes in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the The General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 2/16/23. 2. The laboratory performed an eight analyte Basic Metabolic Panel (BMP) Chemistry test using the Abbott Architect Plus ci4100 analyzer as the primary method and the Abbott i-STAT CHEM8+ cartridge as the back up method. 3. Twice annual comparison of BMP results obtained from the Architect Plus ci4100 and the i-STAT analyzers was required as established on the Quality Assurance Monitor form located in the Lab Quality Assurance Plan manual. The result comparison acceptability criteria was 10% or +/- 4 units as indicated on the Method Comparison form. 4. One of eight analytes did not meet the acceptability criteria during comparisons completed on 11/22/22 and on 02/15/23. See below Date Analyte Values Difference 11/22/22 BUN 23,28 19.6% , 5 units 02/15/23 CO2 25,30 18.18%, 5 units 5. The laboratory did not identify the unacceptable comparison results and failed to perform investigation or correction of the issue. 6. In an interview at 12:45 p.m. on 02/16/23, the GS confirmed the above finding. .